EPO
Epidemiology Program Office
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ADS Newsletter
Office of the Associate Director for Science
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HIPAA Update: Epidemiology Program Office to Host New Health Information Privacy Office at CDC

As nearly everyone in public health practice is aware, the Department of Health and Human Services (DHHS) has issued national health information privacy regulations pursuant to the Health Insurance Portability Accountability Act (HIPAA) of 1996. These regulations, known as the Privacy Rule, became effective on April 14, 2003. The Privacy Rule establishes a uniform floor of privacy protections for identifiable health information. Its coverage centers on health care providers, insurance plans, health data clearinghouses, and their business associates. The Privacy Rule, however, may also apply to others (like public health practitioners) who provide services that are covered under the Privacy Rule (e.g., provision of vaccinations to individuals) in some circumstances.

While the Privacy Rule is the most comprehensive national privacy law introduced in the United States, its

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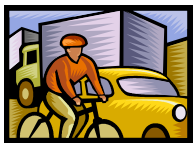

Urban Research Centers

In 1995, CDC established Urban Research Centers (URCs) to assess and improve the health of urban communities. Located in Detroit, New York City, and Seattle, the URCs use an approach called community-based participatory research to engage government, academic, private, and community organizations as partners in setting priorities and designing, implementing, and evaluating community-focused public health research and interventions. Each URC has strong community ties and has enhanced community capacity by developing community research/resource centers.

Example URC Project: LA VIDA—the Southwest Detroit Partnership to Prevent Intimate Partner Violence Against Latina Women—addresses the problem of intimate partner violence (IPV) and the lack of culturally competent prevention and support services for Hispanic/Latina women and their families. Since 1998, representatives from local health and human service agencies, churches, police and criminal justice systems, domestic violence agencies, and academia have mobilized to develop, implement, and evaluate a multi-component, community-based intervention aimed at reducing IPV in Hispanic/Latino families.

Through these centers, URC staff provide training in grant-writing, Research 101, and peer-review boards, and other technical skill development opportunities. These effective and sustainable partnerships address such community-defined priorities as the prevention and management of diabetes, asthma, and

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Ethical Dilemmas in Public Health

Scenario – A CDC investigator was invited by a university professor to participate in a research study. The investigator is also an adjunct faculty member at the university and has collaborated on previous studies at the university. Recently, but before this invitation, the investigator voiced an interest in becoming a full faculty member at the university and is worried about any conflicts or appearance of conflicts of interest if he participates in the study. Another concern is that part of the funding for the proposed study came from a grant from CDC. Personally, the investigator does not feel that his current status and his desire to become a full faculty member will in any way influence the objectivity of his work, and he wishes to participate on the study.

How can the investigator minimize any perceived or real conflicts of interest?

Regardless of whether there is a real conflict, an appearance of conflict can be just as detrimental to a study. The investigator should disclose to the IRBs all potential conflicts of interest and state whether he believes it will have any impact on his work. He should assess whether this potential conflict should be communicated to the study participants, e.g., through the consent process, or whether it is sufficient to disclose to the IRBs and collaborating institution(s). The IRB may request that the information is disclosed to the study participants.

Additionally, separating the funding and research decision processes and responsibilities can help minimize conflicts. An investigator may still be able to work on a project even if there is a conflict if the IRB finds that the conflict does not compromise the research objectivity and human subjects are appropriately protected.

Updated DHHS Guidelines for Ensuring the Quality of Information Disseminated to the Public: Part II, Section D, CDC/ATSDR

Part II, Section D of the Department of Health and Human Service's (DHHS) Guidelines for Ensuring the Quality of Information Disseminated to the Public contains CDC guidelines. The DHHS Guidelines were developed to implement the Office of Management and Budget (OMB) January 2002 requirements that all federal agencies issue guidelines for ensuring the quality of the information that they disseminate to the public. DHHS released the revised Guidelines in November 2003.

CDC Guidelines do not apply to the National Center for Health Statistics (NCHS), the nation's principal health statistics agency, which has separate guidelines http://www.hhs.gov/infoquality/nchs.html.

The guidelines apply to information in all media—print, electronic, audiovisual, and oral. They apply to substantive information, such as studies and reports, rather than to information pertaining to basic agency operations. Information that is disseminated at the request of CDC or with specific CDC approval through a contract, a grant, or a cooperative agreement is subject to these guidelines.

To ensure that CDC is in full compliance with the DHHS Guidelines and other applicable laws and regulations, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), CDC implemented the CDC/ATSDR *Policy on Releasing and Sharing Data* http://basis1.cdc.gov/BASIS/masompb/POLICIES/POLICIES/DDD/385.

The full text of the DHHS Guidelines can be found at the HHS website at: http://www.hhs.gov/infoquality/. Part II, Section D: CDC can be found at http://www.hhs.gov/infoquality/cdcinfo2.htm.

Reminder

A reminder to our investigators: please don't forget to submit a continuation or closure request for any expiring protocol that you may have. Submitting a continuation or closure request for expiring protocol is part of the requirements for investigators conducting human subjects research.

A protocol continuation request must include all of the following:

1. Request for protocol continuation form (CDC form 0.1251);
2. Copy of the currently approved informed consent document (if participants are still being enrolled);
3. Copy of the currently approved protocol (if interaction with participants is still ongoing), reflecting any amendments approved over the past years;
4. If substantive changes have been made to the protocol, consent document(s), data collection instruments, or sites have been added without prior approvals by the CDC IRB, an amendment request (CDC form 0.1252) should be submitted along with the continuation request.

A continuation request should be submitted at least 6 weeks before the expiration date in order to allow sufficient time for the protocol to be reviewed and approved without interruption to the research.

Request for closure (CDC form 0.1253) should be submitted as soon as possible, but before the expiration date.

All CDC IRB forms can be downloaded directly from the CDC Associate Director for Science website at http://www.cdc.gov/od/ads/hsrirb.htm or http://intranet.cdc.gov/od/ads/hsrirb.htm. **For the time being, please use only the MS Word versions from CY 2003 (not pdf versions) because they are the most up-to-date. Older versions do not provide all the information required to process requests for IRB review.**

Upcoming Meetings

- **March 25-27, 2004**

Ethics and Epidemics: An International Conference on the Ethical Dimensions of Epidemic Control

Albany Medical College, Albany, NY, Union College, Schenectady, NY

Information and registration – http://www.union.edu/Academics/Bioethics/News/

- **March 31 — April 1, 2, 2004**

OHRP Conference: Recognizing and Protecting Vulnerable Subjects: Theory, Practice, and Compliance

plus

1-day Pre-conference IRB Workshop: Fundamentals of Human Research Protections

Orlando, Florida

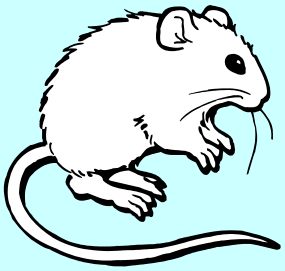
Information and registration — http://www.friendsresearch.org/OrlandoOHRPSaveDate6.pdf

- **April 19-20, 2004**

OHRP Conference, National Human Subjects Protection Conference**:** From the Past to the Future: Evolving Research Issues

Saint Louis, Missouri

Information and registration - http://www.medicine.wustl.edu/~hsc/education/conferenceindex.html



CDC Animal Care and Use Policy

All research involving animals that is conducted by CDC or funded in whole or in part by CDC must comply with the law (Animal Welfare Act) and federal regulations and policies (Public Health Service Policy on Humane Care and Use of Laboratory Animals) regarding animal care and use. This includes research conducted by CDC employees, either internally, or externally, through grants, cooperative agreements or contracts, or in collaboration with outside parties.

The CDC Animal Policy Board (APB) establishes overall policies for animal use at CDC and ensures that CDC is in compliance with federal regulations and policies regarding animal care and use. This board is chaired by the Associate Director for Science, CDC (http://www.cdc.gov/od/ads/animal.htm).

Other APB members include the Chairs from each of the three CDC Institutional Animal Care and Use Committees; the Executive Secretary of Atlanta Institutional Animal Care and Use Committees (IACUC); Director, Office of Health and Safety; Director, Office of Scientific Resources Program, NCID; Chief, Animal Resources Branch, NCID; and the attending veterinarians from each animal facilities (Clifton Road, Chamblee, Lawrenceville, Fort Collins, and Morgantown).

Institutional Animal Care and Use Committees (IACUC)

The Institutional Animal Care and Use Committees are mandated both by the Animal Welfare Act and PHS Policy. They function under the general direction of the CDC Animal Policy Board and have the responsibility to oversee the animal program, facilities, and procedures. CDC has 3 separate IACUCs, in Atlanta, Fort Collins, and Morgantown. Each IACUC is composed of at least 5 members, qualified through experience and expertise to oversee and review activities involving animals. Each IACUC, at a minimum, includes

- A scientist familiar with the use of research animals;
- A veterinarian with delegated program authority;
- A nonscientist;
- An external nonaffiliated member with no other association with the institution; and
- A member of the safety staff from the location.

The responsibilities of the IACUC include, but are not limited to

a. Implementing pertinent decisions of the APB;
b. Conducting initial and subsequent reviews of protocols and protocol amendments submitted for approval;
c. Inspecting facilities and reviewing the overall program, including personnel training, at least twice a year;
d. Advising on upkeep and maintenance of animal facilities, and recommending renovations, expansions, and new equipment as required;
e. Ensuring adequate training for all CDC personnel who deal with laboratory animals and for IACUC members. The IACUC is responsible for providing training for principal investigators and research technicians. They are also responsible for reviewing the training program for animal care personnel;
f. Assuring adherence to standard guidelines for animal care and use as stated in the CDC policy and all referenced materials in the policy.

The *CDC Animal Care and Use Policy* was recently updated and can be found at http://basis1.cdc.gov/BASIS/masompb/policies/revision/DDD/414.

For information on protocol preparation and submission, please visit the Scientific Resource Program, NCID, website at http://www.srp.cdc.gov/ and follow the "Animal Resource" link.

Updated ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication

In November 2003, the International Committee of Medical Journal Editors (ICMJE) released an updated version of the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* (hereafter, referred to as *Uniform Requirements*). The *Uniform Requirements* describes the ethical principles in the conduct and reporting of research and provides recommendations relating to specific elements of editing and writing (Section I.C). The document is meant "to help authors and editors in their mutual task of creating and distributing accurate, clear, and easily accessible reports of biomedical studies." The recommendations in the *Uniform Requirements* will help improve the quality and clarity of manuscripts submitted to any journal. However, ICMJE encourages authors to be familiar with the specific instructions published by the journal they have chosen for their manuscript because every journal has editorial requirements uniquely suited to its purpose.

Section II of the Uniform Requirements describes the ethical principles in conducting and reporting of research. This section defines authorship, contributorship, and editorship. It also emphasizes the importance of editorial freedom and peer review process, as well as conflicts of interest and privacy and confidentiality concerns. The section also briefly mentions "protection of human subjects and animals in research."

Section III discusses publishing and editorial issues, such as obligation to publish negative and positive studies, corrections and retractions, copyright, and overlapping publications, such as redundant and duplicate publications. It also describes correspondence, electronic publishing and advertising in medical

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provisions are supplemented by additional informational privacy laws and policies at the federal, state, and local levels of government. Collectively, these laws and policies seek to balance individual and communal interests in health data. Individuals seek protections for their sensitive, identifiable health data against unwarranted acquisitions, uses, and disclosures. Yet, responsible exchanges of health data are also needed for communal purposes, such as to support clinical treatment, health research, and public health programs and services. Maintaining this balance involves an array of difficult legal, ethical, and policy issues at the intersection of health information privacy and public health.

As a national public health authority, CDC is committed to addressing these issues to assist the agency, its partners, and the public health community. For months, the Epidemiology Program Office (EPO) has designated an official to serve as the agency's HIPAA Privacy Rule Coordinator. Guidance on the impact of the Privacy Rule on public health practice and research was published in an MMWR special supplement in April 2003 (http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm). Forums on the Privacy Rule have been conducted; an internal Privacy Workgroup at CDC has contributed extensively to these and other efforts.

CDC's Office of the Director is committed to furthering the agency's health information privacy interests by establishing a comprehensive Health Information Privacy Office (HIPO) within EPO. Preliminary discussions on the conception and staffing of HIPO led to the drafting of a strategic plan. This plan provides a proposed collaborative framework for accomplishing the underlying bases, functions, and goals of HIPO. Among the office's proposed functions are the following:

- Coordinating, developing, and organizing health information privacy activities, including guidance and policies to be shared within CDC and its partners;
- Reconstituting and overseeing CDC's Privacy Workgroup;
- Acting as a liaison to the Department of Health and Human Service's Office of Civil Rights (which is nationally responsible for implementing the Privacy Rule);
- Developing a modern agenda of health information privacy issues for which the office shall provide guidance;
- Systematically participating in or conducting forums, training sessions, conferences or programs on related topics;
- Working closely with other agency's privacy officials, outside scholars, and policy makers; and
- Serving as a primary resource for questions generating from CDC's staff and other health organizations.

Though the office is still in its formative stages, HIPO staff welcome any questions and comments. Please contact Linda Shelton at lls2@cdc.gov or (404) 639-3683 for more information, or visit the CDC Privacy Rule Website at (http://www.cdc.gov/privacyrule/).

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journals.

Section IV provides general guidance on preparing a manuscript, including general outline, spacing, and contents of title page. Other issues discussed include referencing style and format, tables and figures, and electronic submission of manuscripts.

The full texts of the Uniform Requirements can be found at the ICMJE website at http://www.icmje.org.

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intimate partner violence; access to quality care; and social determinants of health among African Americans, Hispanics/Latinos, Asians and Pacific Islanders, and immigrant and refugee populations. Other accomplishments include significantly contributing to scientific literature on how to build this kind of partnership, community-based participatory research, and process evaluation.

The URCs are currently collecting final data, translating findings, and exploring options for program sustainability. EPO plans to conduct a program evaluation to determine the URCs overall impact on public health.

Next Steps

Early successes in the URCs demonstrate that community-based participatory research is an effective strategy for identifying and systematically addressing urban public health problems. In an effort to look for new ways to promote the concept of community-based participatory research and apply lessons learned from the URCs, the Border Health Promotion Center was established through a $2.2M grant from the Paso del Norte Health Foundation in collaboration with the CDC Foundation. This project seeks to improve health within the Paso del Norte region, which includes El Paso, Texas, Las Cruces, New Mexico, and Ciudad Juarez. The partnership includes leadership and representation from both sides of the border. In response to Healthy Border 2010 goals, the Border Health Promotion Center selected physical activity and environmental health as priorities. Like the other URCs, a CDC liaison is assigned to the site in El Paso, and a CDC project officer is assigned to provide guidance and assistance to the project staff. The board is currently developing it mission, by-laws, and principles. Much can be gleaned from the other URCs, so we will continue to promote cross-fertilization and exchange of ideas and experiences.

For more information please contact Anissa Ham, URC Project Officer, at 404-639-0171 or Aham@cdc.gov.